

-Remarks-

Objection to the Specification:

The Examiner has objected to the specification, alleging that page 122, lines 9 - 11 of the specification refers to methods to assess the biological activity of the compounds of the Examples on page 42. Applicants have amended the specification above to include the correct page reference to the assay method, i.e., page 31, thus obviating the Examiner's objection. Applicants respectfully request that the Examiner reconsider and withdraw the objection to the specification.

The Double Patenting Rejection.

The Examiner has rejected claims 1 - 26, 43 - 46 and 48 - 54 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 24 and 27 of U.S. Patent No. 6,326,359 (hereinafter referred to as "the '359 patent") in view of Jacobson et al., J. Med. Chem., 1992, 35, 407 - 422 (hereinafter referred to as "Jacobson"). The Examiner has specifically alleged that claim 1 of the '359 patent is directed to 5'-alkylated or cyclopropylmethylated adenosine derivatives, wherein A can be  $\text{NR}^a$ ,  $\text{NR}^a\text{C}(\text{O})$ ,  $\text{NR}^a\text{C}(\text{O})\text{NR}^a$  or  $\text{NR}^a\text{SO}_2$ ; and  $\text{R}^3$  is  $-(\text{CH}_2)_p\text{-R}^p\text{-B}$ ; such that  $-\text{A-R}^3$  can be  $-\text{NR}^a\text{C}(\text{O})\text{NR}^b\text{R}^b$ ,  $-\text{NR}^a\text{SO}_2\text{NR}^b\text{R}^b$ , or  $-\text{NR}^a\text{C}(\text{O})\text{CONR}^a(\text{CH}_2)_p\text{-R}^p\text{-B}$ . The Examiner further alleges that the '359 patent does not teach the unprotected hydroxymethyl derivatives or the 5'-uronamide derivatives. The Examiner further alleges that Jacobson teaches that the unprotected hydroxymethyl adenosine derivatives and 5'-uronamide derivatives are agonists of adenosine A2 receptors. The Examiner alleges that it would be obvious to a person of ordinary skill in the art to make and use the unprotected hydroxymethyl adenosine derivatives or the 5'-uronamide derivatives of the compounds of claims 1, 24 and 27 of the '359 patent. The Examiner further alleges that it would also have been obvious to one of ordinary skill in the art to make and use compounds wherein Y is CS or C=N(CN) as such derivatives are well known in the art to be functionally equivalent to CO and are considered well within the purview of the prior art. The Examiner further alleges that it would have been obvious to one of ordinary skill in the art to use any known synthetic method to couple amides or amide equivalents with amines to form ureas or urea derivatives as such synthetic manipulations are considered well within the purview of the prior art.

Applicants have submitted herewith a terminal disclaimer disclaiming the terminal portion of the instant application which extends beyond the expiration date of the '359 patent. Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1 - 26, 43 - 46 and 48 - 54 under the judicially-created doctrine of obviousness-type double patenting.

The 35 U.S.C. §112, first paragraph rejection.

The Examiner has rejected claims 1 - 26, 44 - 46 and 48 - 54 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time of the invention was filed, had possession of the claimed invention. Specifically, the Examiner has alleged that there is not sufficient written description in the specification for the claim to methods of using 5'-uronamides of disubstituted amines for agonizing the adenosine A2a receptor.

The Examiner has also rejected claims 1 - 26, 44 - 46 and 48 - 54 under 35 U.S.C. §112, first paragraph as lacking enablement, i.e., that the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention. Specifically, the Examiner has alleged that the specification does not reasonably enable making or using 5'-uronamides of disubstituted amines.

Without conceding the merits of the Examiner's written description or enablement rejections, Applicants have amended claims 1 and 2 hereinabove, without waiver or prejudice, such that only 5'-uronamides of monosubstituted amides are within the scope thereof and of claims dependent therefrom. Accordingly, Applicants submit that the 35 U.S.C. §112, first paragraph rejections have been obviated.

Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §112, first paragraph rejection of claims 1 - 26, 44 - 46 and 48 - 54, as amended.

The 35 U.S.C. §103(a) rejection.

The Examiner has rejected claims 1- 26, 43 - 46 and 48 - 54 under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,326,359 (hereinafter referred to as "the '359 patent") over Jacobson, J. Med. Chem., 1992, 35, 407 - 422 (hereinafter referred to as "Jacobson"). Specifically, the Examiner has alleged that the '359 patent discloses 5'-alkylated or cyclopropylmethylated adenosine derivatives, wherein A can be  $\text{NR}^a$ ,  $\text{NR}^a\text{C}(\text{O})$ ,  $\text{NR}^a\text{C}(\text{O})\text{NR}^a$  or  $\text{NR}^a\text{SO}_2$ ; and  $\text{R}^3$  is  $-(\text{CH}_2)_p\text{-R}^p\text{-B}$ ; such that  $-\text{A-R}^3$  can be  $-\text{NR}^a\text{C}(\text{O})\text{NR}^b\text{R}^b$ ,  $-\text{NR}^a\text{SO}_2\text{NR}^b\text{R}^b$ , or  $-\text{NR}^a\text{C}(\text{O})\text{CONR}^a(\text{CH}_2)_p\text{-R}^p\text{-B}$  and pharmaceutical compositions containing such compounds and various processes for preparing such compounds. The Examiner also alleges that the '359 patent does not specifically disclose the unprotected hydroxymethyl derivatives or 5'-uronamide derivatives, nor does the '359 patent disclose compounds wherein Y is CS or  $\text{C}=\text{N}(\text{CN})$ . The Examiner alleges that Jacobson discloses that the unprotected hydroxymethyl adenosine derivatives and 5'-uronamide derivatives are agonists of adenosine A2 receptors. The Examiner has alleged that it would have been obvious to one of ordinary skill in the art to make and use compounds wherein Y is CS or  $\text{C}=\text{N}(\text{CN})$  as such derivatives are well known in the art to be functionally equivalent to CO and are considered well within the purview of the prior art. The Examiner further alleges that it would have been obvious to one of ordinary skill in the art to use any known synthetic method to couple amides or amide equivalents with amines to form ureas or urea derivatives as such synthetic manipulations are considered well within the purview of the prior art. Applicants respectfully traverse.

Under 35 U.S.C. §103(c), in effect for applications filed on or after November 29, 1999, subject matter developed by another person, which qualifies as prior art under 35 U.S.C. §102(e), shall not preclude the patentability under 35 U.S.C. 103(c) where the subject matter and the claimed invention were, at the time the invention was made, subject to an obligation of assignment to the same person.

The instant application has an effective filing date in the United States of June 19, 2001. At the time the invention was made, the inventors, Simon John Mantell, Sandra Marina Monaghan and Peter Thomas Stephenson, were each under an obligation to assign their rights in the instant invention to Pfizer Limited.

The '359 patent is a patent granted on an application for a patent by another filed in the United States before the invention by the applicant for the patent. Accordingly The application giving rise to the '359 patent has an effective filing date in the United States of October 5, 1999 (which is an International Application designating the United States of which the application giving rise to the '359 patent is a continuation). At the time that the instant invention was made, the inventors of the '359 patent, Simon John Mantell and Sandra Marina Monaghan, were under an obligation to assign their rights in that invention to Pfizer Limited.

Applicants submit that the '359 patent is a 35 U.S.C. 102(e) reference against the instant application since the inventorship of the '359 patent and the instant application is different. However, since the subject matter of the '359 patent was owned by Pfizer Inc. on June 19, 2001, on which date the inventors of the instant application had each already assigned the instant invention to Pfizer Inc., Applicants submit that the '359 patent is not prior art under 35 U.S.C. §103(c).

Additionally, Applicants have submitted herewith a terminal disclaimer disclaiming the terminal portion of the instant application which extends beyond the expiration date of the '359 patent.

Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §103(a) rejection of claims 1 - 26, 43 - 46 and 48 - 54, as amended.

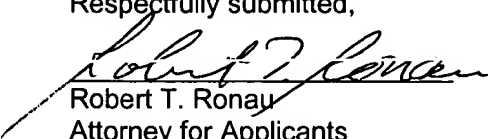
-Conclusion-

Applicants, having responded to all points and concerns raised by the Examiner, believe this application to be in condition for allowance. An early and favorable action is respectfully requested.

Dated: December 2, 2003

Pfizer Inc.  
Patent Department  
Eastern Point Road  
Groton, CT 06340  
(860) 441-5910

Respectfully submitted,

  
Robert T. Ronau  
Attorney for Applicants  
Reg. No. 36,257